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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/646,391 | 08/21/2003 | Martin Gleave | UBC.P-035 | 9734 |
| 21121 | 7590 | 11/10/2005 | EXAMINER | |
| OPPEDAHL AND LARSON LLP P O BOX 5068 DILLON, CO 80435-5068 | | | BOWMAN, AMY HUDSON | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1635 | |

DATE MAILED: 11/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/646,391

Applicant(s)

GLEAVE ET AL.

Examiner

Amy H. Bowman

Art Unit

1635

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 October 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

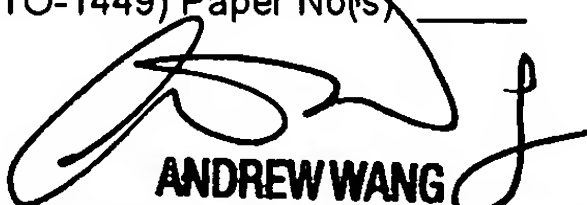
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: _____.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s) _____.
13. ☐ Other: _____.


ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Continuation of 11. does NOT place the application in condition for allowance because: Applicants request for reconsideration has been considered but is not convincing. Applicant's arguments regarding the rejection of claims 1-5 under 35 USC 112, first paragraph, for lacking enablement are not convincing. Applicant argues that the evidence submitted in the 1.132 declaration regarding instant SEQ ID NO: 4 should enable the invention. As explained in the office action mailed on 9/7/2005, the 1.132 declaration does not offer evidence to enable the scope of the instant claims. Specifically, instant claim 1 is not limited to antisense oligonucleotides, but rather is drawn to a method of treatment comprising any therapeutic agent effective to reduce clusterin in melanoma cells. The one specific oligo, SEQ ID NO: 4, exemplified in the 1.132 declaration does not enable a method of treatment with any therapeutic agent, and additionally does not enable the treatment of melanoma with any antisense oligonucleotide. This rejection is maintained for the reasons of record set forth in the office action mailed 9/7/2005.

With regards to the rejections under 35 USC 102 and 35 USC 103, applicant merely asserts that the teachings of the MPEP relied upon by the examiner relate only to composition/article claims or to methods of making. The basis of this assertion is unclear, since the section of the MPEP (MPEP 2112) does not indicate that methods of using are excluded. Additionally, the MPEP makes clear that there must be a manipulative difference and applicant has not demonstrated a manipulative difference between the teachings of the prior art and the instant claims. The recitation of intended use in the preamble of instant claim 1 does not offer any structural difference between the claimed invention and the prior art. Applicant further asserts that in the present case, the preamble cannot be deemed superfluous, since it says what is being accomplished by the method, namely a treatment for melanoma, and the claim without these words is meaningless. Contrary to applicant's assertions, the intended use of treating melanoma does not recite any essential structure or step. The only step recited in the claim is to administer to a subject a therapeutic agent effective to reduce the effective amount of clusterin in melanoma cells. The art cited by the examiner teaches the recited method step and therefore anticipates the invention. This rejection is maintained for the reasons of record set forth in the office action mailed 9/7/2005.